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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,010	11/27/2001	Stanislaw R. Burzynski	BURG:04910379.0049.NPUS00	9045
7590	01/18/2005		EXAMINER	
HOWREY SIMON ARNOLD & WHITE 750 Bering Drive Houston, TX 77057-2198			JONES, DWAYNE C	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/995,010	BURZYNSKI, STANISLAW R.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 September 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14, 15, 17-20, 22-25, 29 and 31 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 14, 15, 17-20, 22-25, 29 and 31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 14, 15, 17-20, 22-25, 29, and 31 are pending.
2. Claims 14, 15, 17-20, 22-25, 29, and 31 are rejected.
3. Claim 29 is objected.

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 14, 15, 17-20, 22-25, 29, and 31 of September 17, 2004 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Objections***

5. Claim 29 is objected to because of the following informalities: it is noted that a comma should be included between "arginine" and "ornithine" in line 3 of this claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 14, 15, 17-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Jaeger of U.S. Patent No. 4,826,680 in view of Schmidl et al. of U.S.

Patent No. 5,719,134. Jaeger teaches of a pharmaceutical composition that contains

riboflavin and the amino acids of glycine, alanine, serine, threonine, valine, and

arginine, (see claims 1 and 4). In addition, Jaeger discloses that this composition has

excellent immunological properties, and is useful in the treatment of cancer, (see

column 1). Jaeger also teaches that this composition contains suitable pharmaceutical

additives and carriers, (see column 3, lines 54-62). In addition, after the prior art

composition of Jaeger is administered the body will naturally metabolize proteins and

oligo-peptides ultimately into individual amino acids. For this reason, the prior art

teaching of Jaeger discloses of the very same components that are instantly claimed,

thus rendering the instant invention obvious. Furthermore, Jaeger specifically teaches

that the amino acids present are hydrolysable, (see claims 1-4). Schmidl et al. of U.S.

Patent No. 5,719,134 is maintained and repeated for both the above-stated and reasons

of record. Schmidl et al. teach of a dietary composition useful for providing nutrition to

individuals with diseases, especially individuals who are unable to consume food orally

and must be fed enterally, (see column 1). Schmidl et al. teach a preferred composition which contains L-arginine, L-alanine, glycine, L-serine, taurine, L-threonine, L-valine, and riboflavin, (see column 4, line 21 to column 5, line 12).

9. The instant claims are directed to composition claims with an intended use of a composition consisting of riboflavin, arginine, and alanine, glycine, serine, threonine, and valine. The prior art reference of Jaeger also teaches of a composition that contains the very same components that are instantly claimed. The only distinction between the prior composition and the instant invention lies with the transitional language of the phrase "consisting of " in the instant application and "comprising" claim language as disclosed by Jaeger and Schmidl et al. Even though the instant composition employs the use of the "consisting" claim language, the prior art reference of Jaeger specifically teach and provide motivation to use riboflavin in the presence of arginine and alanine, glycine, serine, threonine, and valine in order to make pharmaceutical preparations. In addition, Schmidl et al. do teach one having ordinary skill in the art that these claims are pharmaceutical claims with an intended use of treating or reducing the effects of malnutrition associated with a condition or disease, (see column 1, lines 28-30 and lines 37-67). Accordingly, it would have been obvious to the skilled artisan to utilize this nutritional compositions of Jaeger and Schmidl et al. to treat a variety individuals, who suffer from malnutrition due to a disease or condition which causes or is associated with the malnutrition. In addition, it would have been obvious to the skilled artisan to use these well-known amino acids and vitamins to treat individuals from a variety of conditions or ailments where the individual in need thereof

has a reduced dietary intake, which can be due to a variety of reasons, including cancer as well as cancer chemotherapy.

10. Claims 14, 15, 17-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger of U.S. Patent No. 4,826,680 in view of Acosta et al. of U.S. Patent No. 5,550,146. Jaeger teaches of a pharmaceutical composition that contains riboflavin and the amino acids of glycine, alanine, serine, threonine, valine, and arginine, (see claims 1 and 4). In addition, Jaeger discloses that this composition has excellent immunological properties, and is useful in the treatment of cancer, (see column 1). Jaeger also teaches that this composition contains suitable pharmaceutical additives and carriers, (see column 3, lines 54-62). In addition, after the prior art composition of Jaeger is administered the body will naturally metabolize proteins and oligo-peptides ultimately into individual amino acids. For this reason, the prior art teaching of Jaeger discloses of the very same components that are instantly claimed, thus rendering the instant invention obvious. Furthermore, Jaeger specifically teaches that the amino acids present are hydrolysable, (see claims 1-4). Acosta et al. disclose of a nutritional composition, which contains vitamins and amino acids, for the treatment of various metabolic diseases, (see abstract and columns 1 and 2). In fact, Acosta et al. specifically recite the following constituents of taurine and riboflavin, (as cited from Table 1, column 17) and L-alanine, L-arginine, glycine, L-serine, L-threonine and L-valine, (as listed in Table 3, column 21).

11. The instant claims are directed to composition claims with an intended use of a composition consisting of riboflavin, arginine, and alanine, glycine, serine, threonine,

and valine. The prior art reference of Jaeger also teaches of a composition that contains the very same components that are instantly claimed. The only distinction between the prior composition and the instant invention lies with the transitional language of the phrase "consisting of " in the instant application and "comprising" claim language as disclosed by Jaeger and Acosta et al. Even though the instant composition employs the use of the "consisting" claim language, the prior art reference of Jaeger specifically teach and provide motivation to use riboflavin in the presence of arginine and alanine, glycine, serine, threonine, and valine in order to make pharmaceutical preparations. Even though the prior art reference of Acosta et al. is directed to treating inherited metabolic disorders, the compositions of Acosta et al. do teach of pharmaceutical compositions which render the instant invention obvious. In addition, because Acosta et al. do teach that the administration of these nutritional compositions are used to treat metabolic disorders, the skilled artisan would have been motivated to utilize the compositions of Acosta et al. to treat other diseases, ailments or conditions where metabolic disorders are treatable with the administration of dietary, nutritional compositions. Accordingly, it would have been obvious to one having ordinary skill in the art to utilize the nutritional compositions of Jaeger and Acosta et al. to treat metabolic disorders caused by a variety of diseases or conditions, such as cancer.

12. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger of U.S. Patent No. 4,826,680 in view of Copland et al. Jaeger teaches of a pharmaceutical composition that contains riboflavin and the amino acids of glycine, alanine, serine, threonine, valine, and arginine, (see claims 1 and 4). In addition,

Jaeger discloses that this composition has excellent immunological properties, and is useful in the treatment of cancer, (see column 1). Jaeger also teaches that this composition contains suitable pharmaceutical additives and carriers, (see column 3, lines 54-62). In addition, after the prior art composition of Jaeger is administered the body will naturally metabolize proteins and oligo-peptides ultimately into individual amino acids. For this reason, the prior art teaching of Jaeger discloses of the very same components that are instantly claimed, thus rendering the instant invention obvious. Furthermore, Jaeger specifically teaches that the amino acids present are hydrolysable, (see claims 1-4). Copland et al. establish that it is known in the art that 3-phenylacetyl amino-2,6-piperidinedione is an antineoplastic drug, (see abstract).

13. The instant claims are directed to composition claims with an intended use of a composition consisting of riboflavin, arginine, and alanine, glycine, serine, threonine, and valine. The prior art reference of Jaeger also teaches of a composition that contains the very same components that are instantly claimed. The only distinction between the prior composition and the instant invention lies with the transitional language of the phrase "consisting of " in the instant application and "comprising" claim language as disclosed by Jaeger. Even though the instant composition employs the use of the "consisting" claim language, the prior art reference of Jaeger specifically teach and provide motivation to use riboflavin in the presence of arginine and alanine, glycine, serine, threonine, and valine in order to make pharmaceutical preparations. Accordingly, it would have been obvious to the skilled artisan to utilize this nutritional compositions of Jaeger and Copland et al. to treat a variety individuals, who suffer from

malnutrition due to a disease or condition which causes or is associated with the malnutrition, such as cancer. In addition, it would have been obvious to the skilled artisan to use these well-known amino acids and vitamins and antineoplastic agents in various amounts in order to treat individuals from a variety of conditions or ailments where the individual in need thereof has a reduced dietary intake, which can be due to a variety of reasons, including cancer as well as cancer chemotherapy.

14. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger of U.S. Patent No. 4,826,680 in view of Burzynski et al. Jaeger teaches of a pharmaceutical composition that contains riboflavin and the amino acids of glycine, alanine, serine, threonine, valine, and arginine, (see claims 1 and 4). In addition, Jaeger discloses that this composition has excellent immunological properties, and is useful in the treatment of cancer, (see column 1). Jaeger also teaches that this composition contains suitable pharmaceutical additives and carriers, (see column 3, lines 54-62). In addition, after the prior art composition of Jaeger is administered the body will naturally metabolize proteins and oligo-peptides ultimately into individual amino acids. For this reason, the prior art teaching of Jaeger discloses of the very same components that are instantly claimed, thus rendering the instant invention obvious. Furthermore, Jaeger specifically teaches that the amino acids present are hydrolysable, (see claims 1-4). Burzynski et al. establish that it is known in the art that 3-phenylacetylarnino-2,6-piperidinedione is an antineoplastic drug, (see abstract).

15. The instant claims are directed to composition claims with an intended use of a composition consisting of riboflavin, arginine, and alanine, glycine, serine, threonine,

and valine. The prior art reference of Jaeger also teaches of a composition that contains the very same components that are instantly claimed. The only distinction between the prior composition and the instant invention lies with the transitional language of the phrase "consisting of " in the instant application and "comprising" claim language as disclosed by Jaeger. Even though the instant composition employs the use of the "consisting" claim language, the prior art reference of Jaeger specifically teach and provide motivation to use riboflavin in the presence of arginine and alanine, glycine, serine, threonine, and valine in order to make pharmaceutical preparations. Accordingly, it would have been obvious to the skilled artisan to utilize this nutritional compositions of Jaeger and Burzynski et al. to treat a variety individuals, who suffer from malnutrition due to a disease or condition which causes or is associated with the malnutrition, such as cancer. In addition, it would have been obvious to the skilled artisan to use these well-known amino acids and vitamins and antineoplastic agents in various amounts in order to treat individuals from a variety of conditions or ailments where the individual in need thereof has a reduced dietary intake, which can be due to a variety of reasons, including cancer as well as cancer chemotherapy.

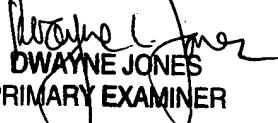
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources.

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DWAYNE JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614  
January 14, 2005